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MCANDREWS HELD & MALLOY, LTD
500 WEST MADISON STREET
SUITE 3400
CHICAGO, IL 60661

EXAMINER	
MEHTA, PARIKHA SOLANKI	

ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,319	ZHANG ET AL.	
	Examiner	Art Unit	
	Parikha S. Mehta	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments and Arguments

1. Applicant's amendments to the drawings are sufficient to overcome the previous objection to the drawings for being informal. Accordingly, the previous objection to the drawings is hereby withdrawn. However, new objections are made to the drawings, the details of which are presented herein.

2. Applicant's arguments with respect to claims 1-65 have been considered but are moot in view of the new ground(s) of rejection.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second pivot assembly must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 2 and 25 recite, in combination with the claims from which they depend, an ultrasound imaging assembly having two pivot assemblies, wherein one assembly is connected to both compression plates, and a second assembly is connected to either one or both plates. The instant specification provides for an embodiment having only one pivot assembly connected to both plates, as well as an embodiment having two pivot assemblies, each connected to only one plate, but the disclosure does not describe, show, or otherwise support an embodiment wherein a first pivot assembly must be connected to both plates and the second assembly is connected to at least one of the plates.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-17, 19-39, 41-44, 46-50, 52-62, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shmulewitz (US Patent No. 5,479,927), hereinafter Shmulewitz ('927), previously cited by Applicant, in view of Adamkowski (US Patent No. 5,706,327), hereinafter Adamkowski ('327), previously made of record.

Regarding claims 1, 3-17, 18-24, 26-39, 42-44, 46-50, 52-62 and 65, Shmulewitz ('927) teaches a system for ultrasound and x-ray mammography comprising a CPU (Fig. 8, col. 11 lines 34-42), first and second compression plates, a breast compression area defined between the compression plates (Fig. 1), and an ultrasound probe having a 2D phased array, wherein the array elements may be individually and sequentially activated (col. 9 lines 15-20, col. 12 lines 14-21). The phased array of Shmulewitz ('927) constitutes an active matrix array wherein the transducer elements are selectively activated as claimed in

the instant application. The lower plate of Shmulewitz ('927) remains in a fixed orientation with respect to the second plate during imaging (col. 7 line 65 – col. 8 line 2). Shmulewitz ('927) teaches the compression plate to be radiolucent (col. 8 lines 40-45), and further shows that the plates are configured to adequately contact the breast without substantially flattening it (Fig. 2). The imaging assembly of Shmulewitz ('927) is secured to a portion of the x-ray mammography system (Fig. 1). The system of Shmulewitz ('927) is upright and configured to image the patient while she is seated or standing, both of which constitute standard mammography positions as claimed in the instant application (Fig. 1). Shmulewitz ('927) provides a plate comprised of sonolucent material (col. 8 lines 40-45), over which an ultrasonic probe may be translated (Fig. 7), and additionally teaches that the bottom stabilization plate has sound-absorbing qualities (col. 12 lines 8-10). Shmulewitz ('927) teaches means for displaying and registering ultrasound and x-ray images of the breast (col. 11 lines 20-33), wherein the system can display a single ultrasound frame or a three-dimensional representation of the breast. The frame and three-dimensional representation of Shmulewitz ('927) constitute an individual slice and a thick slice, respectively, as claimed in the instant application.

Schmulewitz ('927) fails to teach that the two compression plates are angled with respect to each other, and consequently fails to teach any features for the assembly related to the mechanism or adjustment of such an angled arrangement.

In the same field of endeavor, Adamkowski ('327) teaches a mammography system in which the upper compression plate is angled with respect to the lower compression plate (Fig. 2). Adamkowski ('327) angles the upper plate via a pivot and spring assembly (Figs. 3 & 4), which allows for arcuate relative motion between the two plates as claimed in the instant application. Adamkowski ('327) also includes in the assembly an upright member 14 supported by a base 12, and shows that the pivot assembly 34 is connected to an extension member 22, and the compression stage assembly is capable of vertical translation (Figs. 1-4, col. 3 lines 35-37). The extension member is also shown to be perpendicular to the upright member (Fig. 1).

Adamkowski ('327) teaches that the angled plate configuration promotes uniform compression of the breast (col. 1 lines 48-55). In view of such teachings, one of ordinary skill in the art at the time of invention would have found it obvious to modify the system of Shmulewitz ('927) to include the angled compression plate assembly of Adamkowski ('327), in order to improve the uniformity of compression across the patient's breast.

Adamkowski ('327) does not teach that the pivot assembly is attached to each of the compression plates. Rather, the reference pivot assembly attaches one of the plates to a separate support member in

order to effect relative change in the angle between the two plates. Applicant has not disclosed that attaching the pivot assembly to both compression plates instead of attaching it to one plate and a separate support member provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the pivot attached to both plates or the pivot attached to one plate and the separate support member because both arrangements are effective to allow angular motion between the two compression plates. Therefore, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify Shmulewitz ('927), as previously modified by Adamkowski ('327) to attach the other end of the pivot assembly to the second compression plate instead of the support member in order to achieve the claimed invention.

Regarding claims 2 and 25, Adamkowski ('327) teaches of a second pivot assembly comprising a spring attached to one of the compression plates (Figs. 3-5 elements 34a and 34b).

Regarding claims 19, 41 and 64, neither Shmulewitz ('927) nor Adamkowski ('327) explicitly teach imaging in the cranio-caudal and mediolateral oblique planes. However, Applicant admits that it is known in the art to image in the CC and MLO planes during a standard mammography procedure (Specification, p.1 ¶ 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the system of Shmulewitz ('927), previously modified by Adamkowski ('327), to image the breast of a patient in the CC and MLO planes, in view of Applicant's admission of the general state of the art.

8. Claims 18, 40 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shmulewitz ('927) in view of Adamkowski ('327), further in view of Moore (US Patent No. 5,553,111), hereinafter Moore ('111), previously made of record.

Shmulewitz ('927) and Adamkowski ('327) substantially teach all features of the present invention as previously applied to claims 1 and 52. Neither Shmulewitz ('927) nor Adamkowski ('327) provide a swivel member configured to rotate the plates through a plurality of imaging orientations. In the same field of endeavor, Moore ('111) teaches a plate twisting assembly for mammography (Figs. 2A & 2B), wherein the twisting of Moore ('111) is equivalent to the swivel mechanism claimed in the instant application. Moore ('111) teaches that twisting the plates induces a shearing or rolling motion of the breast tissue, which is effective to expose lesions in the breast that would otherwise be undetectable (col. 1 lines 43-52). It would have been obvious to one of ordinary skill in the art at the time of invention to further modify the system of Shmulewitz ('927), previously modified by Adamkowski ('327), to also

include means for twisting the compression plate relative to the base plate so as to more comprehensively image the breast for lesions, in view of the teachings of Moore ('111).

9. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable over Shmulewitz ('927) in view of Adamkowski ('327), further in view of Giger (5,984,870), hereinafter Giger ('870), previously made of record.

Shmulewitz ('327) and Adamkowski ('327) substantially teach all features of the present invention as previously discussed for claim 24. Both Shmulewitz ('327) and Adamkowski ('327) fail to teach a CPU capable of automatically analyzing the ultrasound image data for lesions, cysts, or microcalcifications. In the same field of endeavor, Giger ('870) provides a computer system for automatically classifying breast lesions for diagnosis (Fig. 1). Giger ('870) teaches that automatically classifying breast lesions provides for objective and reliable diagnosis of cancer, and improves the specificity of the cancer screening process (col. 2 lines 42-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the system of Shmulewitz ('927), previously modified by Adamkowski ('327), to also include the automated lesion classification program of Giger ('870), in order to more objectively and reliably diagnose breast cancer in the patient.

10. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shmulewitz ('927) in view of Adamkowski ('327), further in view of Wang (US PG Pubs. No. 2003/0007598), hereinafter Wang ('598), previously made of record.

Shmulewitz ('927) and Adamkowski ('327) substantially teach all features of the present invention as previously discussed for claim 24. Both Shmulewitz ('927) and Adamkowski ('327) fail to provide means for displaying a CINE loop of individual ultrasound slices on the monitor. In the same field of endeavor, Wang ('598) teaches a system for ultrasound mammography, with which a radiologist may manually navigate individual ultrasound slices or view them automatically via a CINE loop (pp 0034). It would have been obvious to one of ordinary skill in the art at the time of invention to further modify the system of Shmulewitz ('927), previously modified by Adamkowski ('327), to also include the CINE loop display feature of Wang ('598) in order to automate and thereby simplify ultrasound image navigation for the radiologist, in view of the teachings of Wang ('598).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha S. Mehta whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Parikha S. Mehta
Examiner – Art Unit 3737

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700